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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,743	05/09/2001	James Nolan	00-388-A	4067

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/27/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/851,743

Applicant(s)

NOLAN ET AL.N

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/10/2003, 10/02, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-13-16, 18-26, 28--31, 33-34 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 13-16, 18, 19, 25, 26, 28-31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 10, 2003 has been entered.

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-34 are pending in this application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-7, 25-26, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "another external body surfaces" in claim 1 is ambiguous as it is not clear to what type of body surfaces is applicant referring? Essentially all external surfaces are covered by skin; therefore, it is not clear to what other types of external surface are the instant method directed? Further, the specification does not provide as to the scope of this phrase or a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

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Step (b) of the process claim 1 is directed to permitting the wound to heal in "the presence or absence of a test compound." This limitation is confusing, because if the test compound is absent then, no comparison can be made about the efficacy of the test drug. Examiner suggest changing this phrase to the presence and absence of a test compound."

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying aldose reductase inhibitors (ARI), does not reasonably provide enablement for identifying any compound that improves treatment of wounds to skin in a diabetic animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors that are to be considered in determining whether a disclosure would require undue experimentation are set forth in *In re Wands*, 858, F.2d 731, 736-40 (Fed. Cir. 1988). Accordingly, they include

1. The quantity of experimentation necessary
2. The amount of direction or guidance presented
3. The presence or absence of working examples
4. The nature of the invention

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5. The state of the prior art
6. The relative skill of those in the art
7. The predictability or unpredictability of the art, and
8. The breadth of the claims.

However, these factors are illustrative, not mandatory and what is relevant depends on the specific facts. All of these factors need not be reviewed when determining whether a disclosure is enabling. *Id.*

The instant claims merely calls for the use of a trial and error to attempt to find a compound that will improve treatment of wound to skin in a diabetic animal. The instant specification first fails to identify potential useful drugs or their mechanism of action for screening. Even though the specification may provide for an exemplary drug from the group of compounds known as ARI, it does not provide necessary link between finding a particular compound or narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.

Second, even though the level of ordinary skill in the art may allow practice of chemical assays to test compounds with potential use, aside from ARIs, particularly the use of 3-(4,5,7-trifluorobenzothiazol-2-yl) methyl-indole-N-acetic acid, no where in the specification provides any guidance to select compounds that are likely to be of use in practicing the claimed invention. Rather, the specification relies on hypothetical level of ordinary skill in the art to supply the missing information. Given the broad breadth of the claims the ordinary skill in the art would not have any guidance as what type of compounds should he proceed with.

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Further, as it has repeatedly been stressed by the Courts, an assay for determining whether a given compound possesses certain desired characteristics and identifies some broad categories of compound that might work, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research." See *Genetech v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, (Fed. Cir.), also *Enzo Biochem, Inc. V. Calgene, Inc*, 1888 F.3d 1362, 1374 (Fed. Cir. 1999). In the instant case, for example at page 11, lines 26-31, specification asserts that "the instant methods can be used to evaluate novel compounds with regard to their effect on wound healing." Thus, similar to the cases above, the instant claims appear to place a function at the point of novelty by identifying a compound that possesses certain desired characteristic. As has been reasoned, such attempt does not satisfy the statutory requirement set forth under 112 1<sup>st</sup> para.

The instant claims do not provide any guidance as to compounds employed, nature of therapeutic activity, and further fail to provide notice for those practicing in the art about the limits of protection. Rather, they simply appear to be an invitation to experiment. Thus, practicing the entire scope of the instant claims require undue experimentation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al US Patent 5,232,341 in view of Jones et al Wo 99/50268 ('268) and Spence US Patent 4,226,232.

Chen discloses methods of assessing the efficacy of topical therapeutic preparation in treating skin wound comprising creating a wound, applying the drug of interest randomly among animals, comparing the rate of healing and assessing the efficacy of the drug (see example 3, col 5-8). Chen does not teach the use of his methodology on diabetic animals. Chen does not teach the employment of his

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methodology in assessing ARI in treating skin wounds associated with diabetic nephropathy.

Jones teaches the use of ARIs in treating diabetic nephropathy. (see page 81, lines 3-23). Specifically, Jones teaches that ARIs can be used to normalize or reduce sorbital accumulation in the sciatic nerve of streptozotocin induced diabetic rats as taught by Mylari et al.

Spence is solely used to show the general knowledge in the art in comparatively assessing agents of choice in treating skin wounds (see col 5, lines 1-47).

Accordingly, even though Chen does not practice his methodology on diabetic animals and explicitly use an ARI, it would have been obvious to one of ordinary skill in the art at the time of invention, to use Chen's method on any animal that shares similar pathophysiological characteristics and further use an ARI for comparative assessment of therapeutic efficacy of other ARIs agents, because as suggested by WO '268, the ordinary artisan would have had a reasonable expectation in observing positive results from such agent in treating diabetic neuropathy. Thus it would have been well within purview of an ordinary artisan in the field of pharmacology to ascertain the relative efficacy of other therapeutic agents in relation to any of the ARIs.

Further, as described by Spence, comparatively determining the pharmacological efficacy of a therapeutic agent in treating skin wounds is routinely practice by ordinary skilled in the art (see col 5, lines 10-50), thus, absence of unexpected results, assessing therapeutic efficacy of drugs in treating skin wound would require the same method steps for any skin etiology including those caused by diabetes.


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***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123

  
RUSSELL TRAVERS  
PRIMARY EXAMINER